

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 09-10179-GAO

UNITED STATES OF AMERICA, ex rel.
CHRISTOPHER DRENNEN,
Relator,

v.

FRESENIUS MEDICAL CARE HOLDINGS, INC.,
d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA,
Defendant.

OPINION AND ORDER
March 19, 2019

O'TOOLE, D.J.

The relator and government allege in this False Claims Act litigation that Fresenius Medical Care Holdings, Inc. ("Fresenius") fraudulently billed Medicare for excessive and medically unnecessary hepatitis B surface antigen ("BsAG") tests. Fresenius has filed two motions to compel discovery of materials that the government has withheld under assertions of the deliberative process and attorney-client privileges.

I. Motion to Compel Testimony of Center for Medicare and Medicaid Services' Corporate Representative

The first motion seeks to compel Dr. Michael Handrigan, the Rule 30(b)(6) designee for the Centers for Medicare and Medicaid Services ("CMS"), to answer questions concerning the substance of conversations he had with his attorneys during a deposition break that preceded a change in his testimony. Fresenius claims that the government waived or admitted the inapplicability of the attorney-client privilege to these communications, but it is apparent from the deposition transcript that the government's purported admission was nothing more than a brief,

and quickly corrected, misunderstanding. The circumstances shown on the record do not come close to an intentional waiver of the attorney-client privilege. The motion is denied.

II. Motion to Compel Documents and Testimony of Government Audit

The second motion seeks the production of documents and deposition testimony related to the government audit of Fresenius laboratory testing and Medicare billing practices for patients with end-stage renal disease (“ESRD”). The audit was announced in late 2007 by the Office of Inspector General (“OIG”) of the Department of Health and Human Services and was conducted by auditors in OIG’s Office of Audit Services (“OAS”).

The audit had two expressed objectives. The first was to determine whether the composite-rate tests that Fresenius had billed for ESRD patients complied with Medicare rules and requirements. The second objective was to gather data on other separately billable tests—i.e., tests not covered by the composite rate—that were commonly provided to ESRD patients, and potentially to report any patterns and trends in the data to CMS. OIG stated that it would issue a final report of its findings concerning the first objective, but that no report would be issued concerning information gathered as to the second objective unless a qualitative assessment of the gathered data was made. In other words, as to the second objective of the audit, OAS from the outset did not anticipate necessarily issuing any concluding report or decision. OAS also requested, and subsequently received from Fresenius, all records of tests relevant to either of the objectives that occurred within the timeframe randomly selected by OAS. Because data concerning separately billed BsAG testing fell within the scope of the second objective, all requested records of those tests during the audit sample period were produced.

In planning and conducting the audit, OAS auditors communicated and exchanged documents among themselves and with attorneys in other government offices, two of which are

particularly relevant here. One was the Office of Counsel to the Inspector General (“OCIG”). OCIG serves as in-house legal counsel to OIG, providing legal advice, representation, and support to its component offices with respect to all aspects of its operations. The other was the Center for Medicare and Medicaid Services Division of the Office of General Counsel (“OGC”). OGC serves as legal counsel to CMS and provides legal advice and counsel to agency personnel on issues relating to fraud and abuse in Medicare and Medicaid programs.

In March 2010, more than two years after the audit was announced, OIG issued as planned a final report regarding the first objective of the OAS study concerning composite-rate tests. It did not issue a report regarding the second audit objective concerning separately billable tests, a quiescence the original plan had contemplated as possible. It did share in an informal way some of the information gathered regarding separately billed tests with Fresenius and with other government officials.

In this litigation the government has produced many of the communications and data from the audit, but it continues to withhold 139 documents and responses to 11 objected-to deposition questions. Briefly put, it claims that all the withheld matters are protected by the “deliberative process privilege” because they are “predecisional” and “deliberative” with respect to the March 2010 report, and that most of them are also protected by the attorney-client privilege because they reflect discussions between auditors and legal staff.

A. Deliberative Process Privilege

The so-called “deliberative process” privilege provides a government agency with protection against compelled disclosure of “documents reflecting advisory opinions, recommendations and deliberations comprising part of a process by which governmental decisions and policies are formulated.” Dep’t of Interior v. Klamath Water Users Protective Ass’n, 532 U.S.

1, 8 (2001) (quoting NLRB v. Sears, Roebuck & Co., 421 U.S. 132, 150 (1975)). Information that is simply factual is generally excluded from protection by the privilege unless it would reveal details of the decisional process. Providence Journal Co. v. U.S. Dep't of Army, 981 F.2d 552, 559 (1st Cir. 1992).

In order for the privilege to apply, the government here must establish that a document is both “predecisional, that is, ‘antecedent to the adoption of agency policy,’” and “deliberative, that is, actually ‘related to the process by which policies are formulated.’” Texaco P.R., Inc. v. Dep't of Consumer Affairs, 60 F.3d 867, 884 (1st Cir. 1995) (quoting Nat'l Wildlife Fed'n v. U.S. Forest Serv., 861 F.2d 1114, 1117 (9th Cir. 1988)).

The privilege is a qualified one. Even if a document is properly characterized as both predecisional and deliberative, its nondisclosure is not automatically justified. Id. at 885. The public interest in protecting the deliberative process must be balanced against the movant's particular need for the information in the litigation. Id.; Ass'n for Reduction of Violence v. Hall, 734 F.2d 63, 66 (1st Cir. 1984). A litigant's showing that the information sought is relevant, helpful, and unavailable from other sources, or essential to a fair determination of a cause, is generally sufficient to overcome the privilege and justify an order of production. See Hall, 734 F.2d at 66.

In the present case, the documents and deposition questions at issue presumably relate either to the composite-rate tests (the first objective of the audit), to other separately billed tests (the second objective), or perhaps to some combination of the two. However, there is no attempt in the government's privilege logs or motion papers to identify which materials relate to which objective.

An informal decision not to pursue a matter to a conclusion, such as the data-gathering audit of the separately billed tests, is not what the deliberative privilege exists to protect. Otherwise almost everything an agency touches could in a broad sense be deemed predecisional and deliberative. Cf. Assembly of Cal. v. U.S. Dep't of Commerce, 968 F.2d 916, 921 (9th Cir. 1992) (“Characterizing these documents as ‘predecisional’ simply because they play into an ongoing audit process would be a serious warping of the meaning of the word.” (quoting Coastal States Gas Corp. v. Dep't of Energy, 617 F.2d 854, 868 (D.C. Cir. 1980))); accord Carter v. U.S. Dep't of Commerce, 307 F.3d 1084, 1090–92 (9th Cir. 2002).

The policy purpose that justifies the limited privilege is essentially threefold:

[I]t serves [i] to assure that subordinates within an agency will feel free to provide the decisionmaker with their uninhibited opinions and recommendations without fear of later being subject to public ridicule or criticism; [ii] to protect against premature disclosure of proposed policies before they have been finally formulated or adopted; and [iii] to protect against confusing the issues and misleading the public by dissemination of documents suggesting reasons and rationales for a course of action which were not in fact the ultimate reasons for the agency's action.

Providence Journal, 981 F.2d at 557 (1st Cir. 1992) (quoting Coastal States, 617 F.2d at 866).

None of these reasons is furthered by precluding disclosure of the data regarding the separately billed tests gathered in the course of the audit because the government has not demonstrated that any agency policy or decision was made on the basis of that data.

To the extent the materials for which protection is claimed do not pertain only to the separately billed test study, there is a dispute whether the materials are relevant to Fresenius' asserted defenses of materiality and government knowledge. See, e.g., Universal Health Servs., Inc. v. United States, 136 S. Ct. 1989, 2003 (2016) (“[I]f the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material.”).

The balance of interest inquiry that is appropriate with regard to the qualified privilege tilts in Fresenius' favor. The government's generally stated interest in withholding the materials at issue, which are now ten years old and concern regulations that have long since been amended, weighs little against Fresenius' present interest in defending against the pending claims of fraud.

The government's objections to discovery, whether by document disclosure or answers to deposition questions, that are based solely on an assertion of the deliberative process privilege are overruled.¹ Those documents are to be produced.

B. Attorney-Client Privilege

Fresenius makes three separate arguments related to materials withheld under a claim by the government of the attorney-client privilege: (A) that the matters are merely "neutral, objective analyses of agency regulations" to which the privilege does not apply, see Coastal States, 617 F.2d at 863; (B) that communications between OIG and CMS were not made in the course of a genuine attorney-client relationship; and (C) that OCIG attorney Nicole Caucci was not providing legal advice but only factual information to OIG auditors.

The information in the parties' briefing is not sufficient to permit the Court to make reliable assessments about the appropriateness of any particular attorney-client privilege claim. Accordingly, within seven days of the entry of this Order, the government is directed to submit *ex parte* a sample consisting of the following documents for *in camera* review by the Court:

1, 7, 22, 25, 31, 44, 47, 49, 59, 79, 80, 86, 110, 111, 112, 113, 114, and 115.

III. Conclusion

For the reasons stated, the Motion to Compel Testimony of CMS' Corporate Representative (dkt. no. 297) is DENIED. The Motion to Compel Production of Documents and

¹ Privilege log lines 4, 5, 14-21, 28, 34, 46, 48, 50, 54-56, 64-71, 92-99, and 107-109.

Testimony (dkt. no. 299) is GRANTED insofar as the documents withheld only on the grounds of deliberative process shall be produced, and otherwise RESERVED regarding the government's assertion of the attorney-client privilege.

It is SO ORDERED.

/s/ George A. O'Toole, Jr.
United States District Judge